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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,557	02/10/2004	Peter Nash	C150.12.4	1455

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,557	NASH ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 29, 2010 has been entered.

Amendment Entry

2. The amendment filed March 29, 2010 has been entered. Claims 1-60 are cancelled. Claims 61-72 are newly added. Claims 61-72 are under consideration in this Office action.

Withdrawal of Objections and Rejections

3. The following rejections have been withdrawn in view of applicants' amendments:

a) The new matter rejection of claims 49-58 under 35 USC 112, first paragraph;

b) The rejection of claims 1,5, 7-9, 42, 45-47, 49-52 and 54-58 under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Okuno et al;

c) The rejection of claims 1, 5, 7-9, 42, 45-47, and 49-58 under 35 U.S.C. 103(a) as being unpatentable over Tokoro in view of Okuno et al;

d) The rejection of Claims 8-10, 46-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee, Okuno et al., and Coleman further in view of Ishihara et al;

e) The rejection of claim 58 under 35 U.S.C. 112, second paragraph; and

f) The objection of claims 53 and 58.

Response to Arguments

4. Applicant's arguments with respect to claims 1-60 have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection Necessitated By Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 61-62, 65, 67-68, 70 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., (US Patent 4,748,018 published May 31, 1988) and Emery et al., (US Patent 5,420,253 published May 30, 1995) in view of Van Donkersgoed et al. (Can Vet. J. Vol. 36. July 1995. pages 425-429).

The claims are drawn to a method of decreasing animal respiratory illness by inhibiting the ability of target colony-forming organisms to adhere to the mucous membranes and bronchi and alveolar cells of the respiratory tract of an animal to reduce the ability of the organisms to multiply wherein said colony-forming organisms are

composed of an organism mixture of *Pasteurella Haemolytica, Pasteurella Multicoda,* and *Haemophilus somnus.*

Stolle et al., (US Patent 4,748,018) teach a method for passively immunizing a mammal with heterologous antibody obtained from an immunized domesticated fowl, which has been immunized against an antigenic substance (col.1 lines 10-13, col. 3, lines 39-45). Any antigen or combination of antigens can be employed, where the antigen can be bacterial, viral, cellular or any other substance to which the immune system of the fowl will respond (col. 5 lines 1-5). Suitable antigens can include *Pasteurella haemolytica, Pasteurella multicoda* and several *Haemophilus* species, along with a wide variety of other known antigens (col. 5 lines 10-35). The method teaches feeding the mammal a material having an enhanced antibody titer against an antigen obtained from the egg of fowl immunized against the antigen and administering to the mammal an immunologically effective amount of antibody (col. 3 lines 50-65). Example 1 teaches using mixed bacterial strains for inoculation of the birds. Stolle et al., teach antigen selection; sensitatization of the domesticated fowl by primary immunization; Testing of the eggs or serum to confirm sensitivity induction; administration of boosters to induce and maintained an antibody producing state; testing of the antibody level in the egg yolk; and collecting the eggs during its immunized state (col. 7-8, lines 25-35). The purified antibody has been sterilized and subjected to filtration (col. 8, lines 30-35). Stolle et al., teach preparation by way of pasteurization of immune milk containing enhanced antibodies (col. 8, lines 42-54). The egg product or antibody comprises a parenteral carrier (col. 4, line 18). This method is applicable to human beings also (col.

4 lines 66-68). Modes of administration include oral and parenteral administration (col. 6 lines 40-45). It is noted that parenteral administration involves piercing the skin or mucous membrane, while oral administration includes administration to the enteral/digestive tracts and respiratory tracts (including bronchi, alveolar sacs and alveoli) using liquids, such as inhalers, nebulizers, vaporizers, and the like. Oral administration can also be effectively used to treat diseases (col. 6 lines 45-46). Those of skill in the art can readily ascertain the amount of egg product, or avian antibody, to give to the mammalian subject (col. 7 lines 8-11). Stolle et al., teach the compositions can bee used in the form of premixed food products such dehydrated immune milk or egg materials and can be mixed and used either in the feeding stage or administration stage (col. 9, lines 4-9).

Emery et al., teach immunizing a bird to provide passive immunity protection against a bacterial pathogen, such as with *Pasteurella multicoda* and Haemophilus species (col. 4, lines 3-3 and col. 9, lines 45-48). Emery et al., teach the avian-derived immunoglobulins provides a higher level of specificity and a reduced amount of undesirable side effects as compared to immunoglobulins derived from mammalian serum (col. 1, lines 10-15). passive immunization Emery et al., teach immunization will stimulate the female bird to produce eggs containing a high level of the immunoglobulin of interest, resulting in eggs being separated and purified (col. 4, lines 45-50). Emery et al., teach albumen, IgM, IgA and IgG locations and separation from the shell and yolk (col. 4, lines 56-68). Emery et al., teach combining the egg resulting product with physiologically acceptable carriers, other additives, including preserving agents such as

bacteriostats, fungistats and the like and adjuvants as necessary (col. 8, lines 22-35). The composition may be administered orally, parenterally, or by respiratory aerosolization (col. 9, lines 14-17). However while both Stolle et al., and Emery et al., teach the use of *Haemophilus* antigens, neither specifically recite *Haemophilus somnus.*

Van Donkersgoed et al., teach vaccination protocols on passive immunity to *Pasteurella haemolytica* and *Haemophilus somnus* for combined vaccination. Van Donkersgoed et al., teach higher antibody titers in animals receiving passive administration receiving the combined vaccine (page 424, col.1). Van Donkersgoed et al., teach the level of antibodies achieved by vaccination also depends on the efficiency of passive transfer (page 424, col.2).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with *Haemophilus somnus* as taught by Van Donkersgoed et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by Stolle et al., and Emery et al., in order to provide more efficient passive immunization results. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Emery et al., teach the desire to produce the avian-derived immunoglobulins for pharmaceutical applications in the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., and Emery et al., teach primary immunization with multiple specific antigens, such as the respiratory organisms, wherein all the claimed elements were

known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Finally it would have been prima facie obvious to combine the teachings of Stolle, Emery and Van Donkersgoed et al., to advantageously decrease animal respiratory illness and reduce the ability of the organisms to multiply after immunization.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 66 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Kirkwood et al., (J. of Swine Health and Production. Vol. 9(2):77-79).

Stolle et al., Emery et al., and Van Donkersgoed et al., have been discussed above, however while the references teach using *Haemophilus,* none specifically recite *Haemophilus suis*.

Kirkwood et al., teach the *H. parasuis* bacteria colonize mucosal surfaces such as the nasal mucosa and trachea (page 77, col.1). Kirkwood et al., teach passive immunity is essential for protection against *H. parasuis* challenges (page 77, col.2). Kirkwood et al., teach *H. parasuis* is also known as suis (page 79, col.1). It is noted, the instant specification refers to the preparation of the *Haemophilus suis* antigen, but the ATCC 19417, *Haemophilus parasuis* as the stock antigen.

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate inoculation with *Haemophilus suis* as taught by Kirkwood et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by the prior art references in order to provide more efficient passive immunization results. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., and Emery et al., teach the desire to produce the avian-derived immunoglobulins for pharmaceutical applications in the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., and Emery et al., teach primary immunization with multiple specific antigens, such as the respiratory organisms, wherein all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Finally it would have been prima facie obvious to combine the teachings of Stolle,

Emery, Van Donkersgoed et al., and Kirkwood to advantageously decrease animal respiratory illness and reduce the ability of the organisms to multiply after immunization.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Nash et al., (US Patent Application Publication 2002/0098181).

Stolle et al., Emery et al., and Van Donkersgoed et al., have been discussed above, none specifically recite adding molasses to the contents of the harvested eggs.

Nash et al., teach a microbial adherence inhibitor in the form of fowl egg antibodies made by inoculating female birds with the immunogen, after a period of time sufficient to permit production on the bird of antibody to the target immunogen, harvesting the eggs which contain antibodies to the immunogen, separated the eggs from the shells, drying the egg contents and adding to the feed or water for the host animals [para. 0028]. Nash et al., teach the inhibitor product can be used in almost any

kind of feeding program, and works well is feed additives such as molasses [para. 0034]. Example 20 teaches pasteurized egg products. Example 21 teach supplying the egg product in a dried formatted, using a carrier to help distribute the material in a uniform method, which makes it easier for mixing with standard feeds. A number of carriers can be used wherein the production is pasteurized and coated onto the carrier [para. 0065].

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate adding molasses to the contents of the egg product as taught by Nash et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by the prior art references in order to better distribute the egg product material in a uniform method to the receiving animals. One of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention since Stolle et al., Emery et al., and Nash et al., teach the production of avian-derived immunoglobulins for pharmaceutical applications in the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., Emery et al., and Nash et al., teach primary immunization with specific organisms, such as the respiratory organisms, and all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stolle et al., Emery et al., and Van Donkersgoed et al., as applied to claims 61 and 68 above, and further in view of Smith et al., (Infection and Immunity. 2001. Vol.69(5): 3135-3142).

Stolle et al., Emery et al., and Van Donkersgoed et al., have been discussed above, none specifically recite adding the specific preservatives.

Smith et al., teach passive transfer of IgY antibody confers protection against bacterial infections. Passive administration of chicken egg yolk IgY antibody protects rats from experimental dental caries infection (page 3135). Smith et al., teach administering the immune IgY together with sodium benzoate to the rats (page 3137).

Therefore, it would have been prima facie obvious to one ordinary skill in the art at the time the invention incorporate the preservative sodium benzoate to the contents of the harvested egg as taught by Smith et al., to the method of decreasing animal respiratory illness by inhibiting the ability of the organisms to adhere to mucous membranes, bronchi and alveolar cell as taught by the prior art references in order to act as a preservative within the pharmaceutically acceptable carrier. One of ordinary skill in the art would have had a reasonable expectation of success in producing the

claimed invention since Stolle et al., Emery et al., and Smith et al., teach the production of avian-derived immunoglobulins for pharmaceutical applications in the treatment of other animals. Furthermore, one having ordinary skill in the art would have been motivated to make such a combination because Stolle et al., Emery et al., and Smith et al., teach primary immunization with specific organisms, followed by immunization with the egg product to another animal where all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi, can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645